REMARKS

This is in response to the Office Action mailed on March 2, 2004 by the United States Patent and Trademark Office setting a three-month period for response which was set to expire on June 2, 2004. The three-month shortened statutory period for response is extended by one month to July 2, 2004 pursuant to the Petition for Extension of Time Under 37 C.F.R. §1.136(a) which is submitted herewith.

Claims 1-12 were in the application as filed. Claims 13-23 were added, and claim 12 was cancelled in the Preliminary Amendment filed on February 15, 2002. Claims 1, 5, 7, 8, 13, 17, 19, and 20 were cancelled without prejudice on November 21, 2003.

Claim 11 has been amended in order to correct an obvious typographical error in the word "befloxatome" which now correctly reads as "befloxatone."

Claims 14-16, 18, and 21-23 are cancelled. Claims 2-4, 6, and 9-11 remain in the application.

Claims 14, 15, 16, 18, 21 and 22 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 2, 3, 4, 6, 9, and 10, respectively. The objection is rendered moot by the cancellation of said claims.

Claim 23 is objected to as being dependent on claim 22, also objected to. The objection is rendered moot by the cancellation of claim 23.

Claims 2-4, 6, and 9-11 continue to be rejected under 35 U.S.C. § 103(a) as being unpatentable over Wurtman et al., U.S. Patent No. 4,999,382, in view of Benedetti et al., Advances in Drug Research 23, 65-125 (1992) based on essentially the same grounds as cited by the examiner in the Office Action mailed on May 21, 2003. With respect to Applicant's response dated November 21, 2003, the Examiner now contends the following:

> First, applicant argues that Wurtman et al. is directed to the suppression of weight gain usually associated with the cessation of tobacco use. In addition, applicant purports that Wurtman et al. do not teach or suggest the use of MAO inhibitors to decrease the body weight of an obese patient, especially, for example, one, who was not a tobacco user. Wurtman et al. specifically teach that it is well established in the art that the neurotransmitter of serotonin (5-HT) modulates a variety of body systems, glands, neurons. In fact, Wurtman et al. specifically disclose that the serotoninergic neurons are involved with inter alia, appetite, (see column 2, lines 42-53). The methods described in Wurtman et al. are directed to the administration of compounds that are effective in decreasing weight gain and the consumption of high carbohydrate foods, (see column 3, liens 47-57). Wurtman et al. specifically recite that there is a decrease in weight gain and even a lower consumption of high carbohydrate foods by the administration of serotoninergic drugs, (see column 4, lines 3-51). This teaching clearly provides one skilled in the art with the motivation to use compounds that are known to have an effect of enhancing serotonin-mediated neurotransmission, which embraces compounds that are serotonin reuptake inhibitors as well as inhibitors of monoamine oxidase. Accordingly, the instant claims are obvious in view of these teachings from Wurtman et al.. Consequently, the skilled artisan is provided with the motivation to employ these compositions to treat obesity as instantly claimed.

This rejection is traversed and reconsideration and withdrawal thereof are requested for the reasons given hereinbelow.

Wurtman et al. is directed to the suppression of the weight gain usually associated with cessation of tobacco use. The reference indicates that the entire premise for using the disclosed "serotoninergic" compounds to suppress weight gain and recidivism after cessation of tobacco use is due to an increased number of receptors for nicotine (and, consequently, for acetyl

choline) in tobacco users. Hence, after the cessation of nicotine use, the serotoninergic neurons are firing less frequently and releasing less serotonin. However, the disclosure does not teach or even suggest the use of such "serotoninergic" compounds to suppress weight gain when an increase in receptors for nicotine due to tobacco use is absent, such as in non-tobacco users. Moreover, Wurtman et al. do not suggest that these "serotoninergic" compounds are capable of suppressing weight gain in individuals who use tobacco, but are not experiencing nicotine withdrawal. Thus, relying upon Wurtman et al.'s disclosed theory, nothing would motivate one skilled in the art to use "serotoninergic" compounds to treat obesity, much less to use MAO inhibitors specifically, in a person who is not experiencing an increase in the number of receptors for nicotine from tobacco use.

Furthermore, nowhere in the reference is there a suggestion that any MAO inhibitor, let alone those of the instant claims, would be useful in treating obesity. At most, Wurtman et al. might have made it obvious to try using an MAO inhibitor to determine if it was effective in reducing weight gain and recidivism when a person stops using tobacco, but in no way would it have suggested the use of one of Applicant's MAO inhibitors to decrease the body weight of an obese patient, especially, for example, one who was not experiencing tobacco withdrawal. This is an important distinction, since decreasing body weight gain in an obese individual is different from merely decreasing weight gain and lowering consumption of high carbohydrate foods. This dissimilarity is illustrated by Example 3 on pages 7-8 of the Applicant's specification.

Example 3 describes an experiment in which both lean rats and obese rats were treated for five weeks with an MAO inhibitor, namely befloxatone. The results of this experiment displayed a significant reduction of body weight gain in obese rats over a five-week period *without* a significant reduction in food intake. The lean rats, however, displayed both a *similar*

significant reduction in body weight gain as well as a significant decrease in food intake for two weeks of the experiment. Thus, the experiment demonstrates obese rats reacting differently than non-obese rats to the same exact treatment, and hence, demonstrates an example of the distinction between the treatment of obesity and the mere prevention of weight gain. The fact that Wurtman et al. disclose the use of certain drugs to decrease wait gain and recidivism in individuals also experiencing tobacco withdrawal, just offers and an additional distinction from the instant invention.

The examiner continues responding to Applicant by stating:

> Moreover, the instant claims not only are directed to treating obesity but are open-ended with the word comprising. Applicant recites the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim." *Gould v. Mossinghoff, Comr. Pats.,* (DCCD 1982) 215 USPQ 310. For this reason, the instant claims cover additional components and do not rule out that a tobacco smoker could be treated for weight loss, as disclosed in the prior art rejection of Wurtman et al. in view of Benedetti et al.

Firstly, Applicant does not agree with the examiner that Wurtman et al. disclose a weight loss treatment for a tobacco smoker. The Wurtman reference only discloses methods of providing weight loss and suppressing weight gain associated with the cessation of tobacco use, and not for weight loss in a mere tobacco smoker.

Applicant does agree, however, that the word "comprising" relates to open-claim language, as stated by the examiner. Nevertheless, the instant claims are clearly limited to methods of <u>treating obesity</u> by administering a monoamine oxidase inhibitor. Wurtman et al. disclose a treatment to the symptoms of tobacco cessation, one of which symptoms is weight

gain. Again, there is no suggestion in Wurtman, that any MAO inhibitor can be used to treat obesity. Hence, the use of the word "comprising" does not render the claims obvious, since the cited references do not suggest a treatment of obesity; one of the instant claims' limitations.

Lastly, Benedetti et al. is cited by the examiner:

> Second, applicant argues that the only eating disorders referred to in Benedetti et al. are anorexia and bulimia, two conditions that are largely irrelevant to obesity. However the rejection of record is Wurtman in view of Benedetti et al. Because Wurtman et al. teach to the skilled artisan to utilize serotoninergic compounds, which includes inhibitors of MAO, for the treatment of weight gain, the prior art reference of Benedetti et al. was used to simply provide additional examples of inhibitors of MAO. It would have been obvious to one having ordinary skill in the art, especially in view of the Wurtman et al., to use other serotoninergic compounds, which includes inhibitors of MAO, including those listed in Benedetti et al.

The secondary reference, Benedetti et al., Advances in Drug Research 23, 65-125 (1992), is cited by the examiner to provide additional examples of inhibitors of MAO. Although this reference does list several examples of inhibitors of MAO, it fails to make Applicant's claimed invention obvious either alone, or in view of Wurtman. There is no motivation to pick any inhibitors of MAO listed in the Benedetti reference for the use in treating obesity, since neither reference suggests any such use, whether alone or in combination. Accordingly, Benedetti et al. adds nothing to Wurtman et al., and the cited references together would not have suggested the invention here claimed.

In view of the foregoing remarks, reconsideration and withdrawal of the rejection of 2-4, 6, and 9-11 under 35 U.S.C. §103(a) is respectfully requested. There being no remaining issues, this application is believed in condition for favorable reconsideration and early allowance, and such actions are earnestly solicited.

Respectfully submitted,

Dated: 6/21/04

Paul E. Dupont
Registration No. 27,438

Sanofi-Synthelabo Inc.
Patent Department
9 Great Valley Parkway
P.O. Box 3026
Malvern, PA 19355
Tel.: (610) 889-6338
Fax: (610) 889-8799